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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,761	12/30/2003	D. Russell Pflueger	D-3090	2723

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EXAMINER

LOPEZ, AMADEUS SEBASTIAN

ART UNIT	PAPER NUMBER
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3771

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/748,761	Applicant(s) PFLUEGER, D. RUSSELL	
	Examiner Amadeus S. Lopez	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 3,7-12 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4, 5, and 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/19/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 3, 7-12 and 17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/25/2006. The examiner acknowledges the applicant's selection of species 3, shown in figures 3A-3C with traverse. In response to the argument that all of the present apparatus shown or illustrated in the drawings of the instant application, are for maintaining patency of a vessel or other region of a human body or animal body and should therefore all the claims should be examined, searching for each feature of the different embodiments of the device would result in a burden on the examiner.

Therefore the election of species requirement is maintained. Further, the applicant states that all of the present claims 1-17 read on species 3. The examiner disagrees. Claims 7-12 and 17 refer to "a plurality of struts" and "providing another one of said at least one elongated member (which the examiner interprets to be the struts)," which is drawn to alternate embodiments such as the embodiments shown in figure 5 and 6A-E. Further at no point in the description of species 3 in the specification is the term strut ever used. The applicant refers to a mesh material that would not read on a strut. With regards to claim 3, the limitation "defines a substantially flat oblong configuration when in other than the deployed configuration," is drawn to figures 5 and 6D as stated on page 17, line 8-13. Since the applicant has chosen the figure 3 embodiment, the claims 3, 7-12 and 17 have been withdrawn and claims 1-2, 4-6 and 13-16 are to be examined.

Information Disclosure Statement

The examiner has considered all references disclosed within the Information Disclosure Statement filed on 11/19/2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

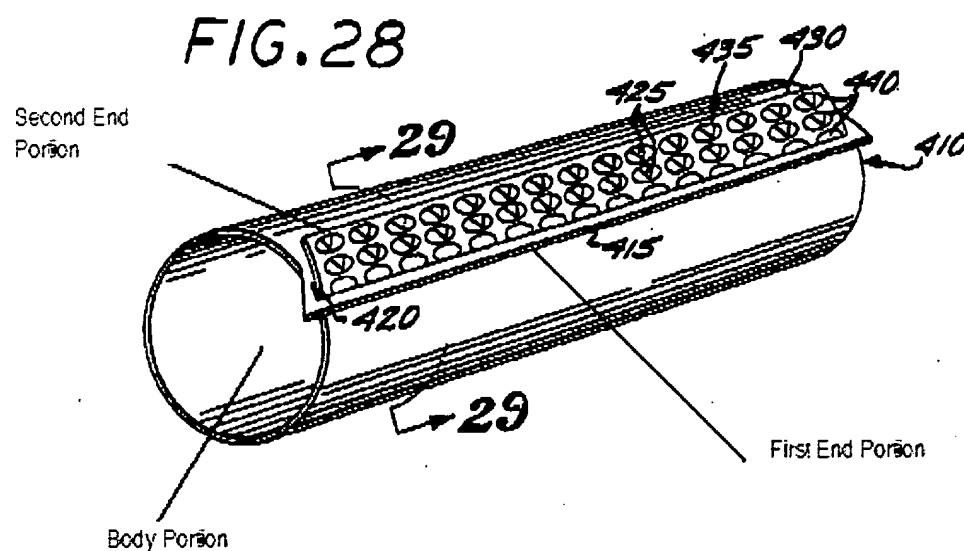
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Khosravi et al (5618299).

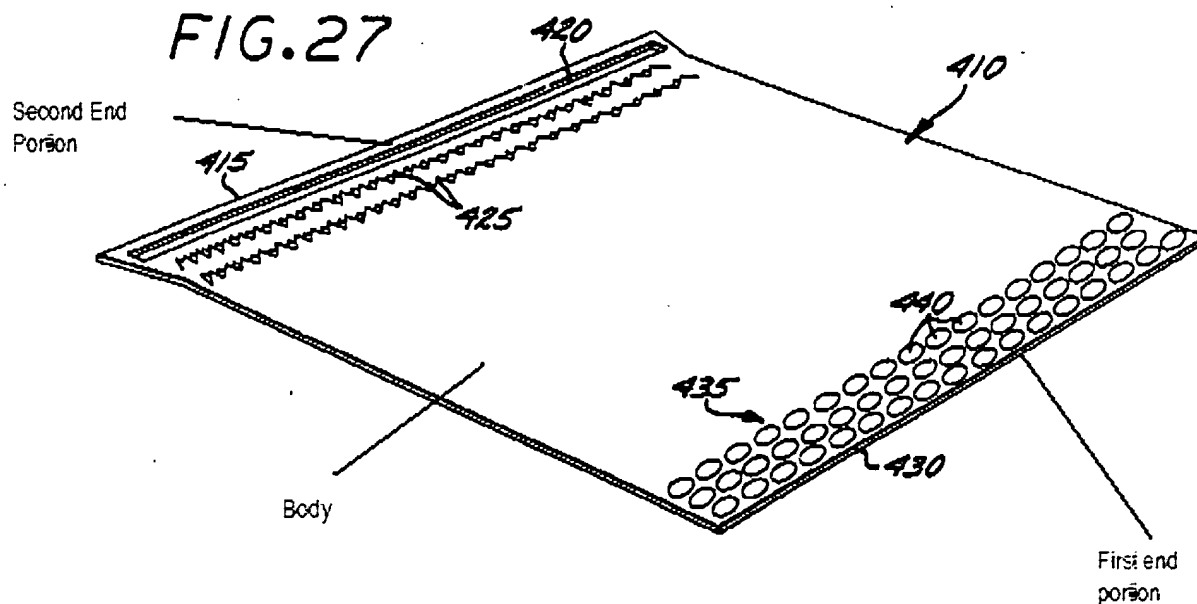
As to claim 1, Khosravi et al disclose an apparatus for maintaining patency of a vessel or other region of a human or animal body, the apparatus comprising: an appliance (410) comprising a body portion (labeled in figure 28 below) and end portions (labeled in figure 28 shown below) spaced apart by the body portion, the appliance being structured to take on a deployed configuration when located within the vessel or other body region, such that the end portions are spaced apart from each other by other than the body portion, the end portions overlap each other, or the end portions directly contact each other, and the appliance being further structured to exert a force in the vessel or other body region, when the appliance is in the deployed configuration within

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the vessel or other body region (See figure 28), in order to maintain the region substantially open or unobstructed, or to cause the region to be maintained substantially open or unobstructed (Col. 1, lines 40-45).



As to claim 2, Khosravi et al disclose an apparatus for maintaining patency of a vessel or other region of a human or animal body wherein the appliance is structured to form a relatively flat configuration (see figure 27 below).



As to claim 4 and 5, Khosravi et al disclose an apparatus wherein the appliance comprises a super-elastic material, which in this case is disclosed to be Nitinol (Col. 6, 28-40).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6, 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi et al in view of Roth (6406490).

As to claim 6, Khosravi et al disclose an apparatus with all the limitations of claim 1 with the exception of wherein the end portions are radiused. Roth discloses a stent for maintaining patency of a body vessel with radiused ends (Col. 6, lines 24-28). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the ends of Khosravi et al's device so that it will "help distribute the point force imparted on the vessel wall and reduces the risk of vascular injury that arises with the use of square edges," as taught by Roth.

As to claim 14, Khosravi et al disclose a method for maintaining patency or causing to become patent, open or unobstructed, a body region of a human or an animal, the method comprising the steps of: providing a flat or pre-curved member having a body portion and end portions spaced apart by the body portion (Figure 28 above shows it in the flat configuration); pulling end portions of the flat or pre-curved member together to form a folded configuration (Figure 27 shown above); holding or temporarily securing the end portions together (Figure 27); placing the member in the folded configuration, into a body region to be treated (Col. 1, lines 40-45); and releasing the end portions from being held or secured together, thereby allowing the member to expand within the body region (Col. 1, lines 40-45). Since Khosravi et al disclose an

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apparatus with all the structural limitations of the device of the instant application, the method steps would have been obvious by the use of the device as taught by Khosravi et al.

As to claim 15, Khosravi et al disclose a method for maintaining patency wherein the expanded member within the vessel or other body region is effective to provide a substantially constant radial force against the walls or tissues of the body region (it is inherent that the stent of Khosravi et al provides a substantially constant radial force against the walls or tissues of the body region based on its elasticity and mechanical properties). Since Khosravi et al disclose an apparatus with all the structural limitations of the device of the instant application, the method steps would have been obvious by the use of the device as taught by Khosravi et al.

As to claim 16, Khosravi et al disclose a method for maintaining patency or causing to become patent, open or unobstructed, a vessel of a "human or animal, the method comprising the steps of: providing at least one elongated member having a desired stiffness and resiliency, implanting the elongated member submucosally into walls of the vessel in alignment with a longitudinal axis (Col. 1, lines 40-45; Col. 3, 19-27). Since Khosravi et al disclose an apparatus with all the structural limitations of the device of the instant application, the method steps would have been obvious by the use of the device as taught by Khosravi et al.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Khosravi et al as applied to claim 1 above, and further in view of Zafrir-Pachter et al (2004/0010308).

As to claim 13, Khosravi et al disclose and apparatus with all the limitations of claim 13 with the exception of wherein the appliance comprises a cuff-shaped member having an outer peripheral portion defining an interior space. Zafrir-Pachter et al disclose an apparatus wherein the appliance comprises a cuff-shaped member (20; Fig. 3A and 3B; cuff shaped when in configuration shown in 3A) having an outer peripheral portion (where arrow 21 is pointing in figure 3B) defining an interior space (27).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the apparatus of Khosravi et al to include a cuff-shaped member having an outer peripheral portion defining an interior space because it is well known in the art as taught by Zafrir-Pachter to include an interior space within the apparatus. Further, the Khosravi et al reference discloses the claimed invention except for having the appliance comprise a cuff-shaped member having an outer peripheral portion defining an interior space. It would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to have the apparatus in such a configuration, since the applicant has not disclosed that doing so solves any stated problem or is of any particular purpose and it appears that the invention would perform equally well with the ratchet configuration without an interior space as disclosed by Khosravi et al.

Conclusion

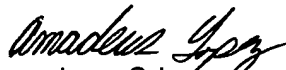
The prior art made of record and not relied upon is considered pertinent to the applicant's disclosure. US 5441515, US 6312463, US 5007926, US 6793672, US 2004/*0010308, and US 5059211 are cited to show different stents.

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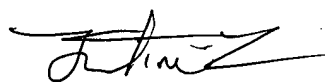
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amadeus S. Lopez whose telephone number is (571) 272-7937. The examiner can normally be reached on Mon-Fri 8:00AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Amadeus S Lopez
Examiner
Art Unit 3771
November 7, 2006

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11/8/06